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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/698,230

10/31/2003

Min Wan

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05/23/2006

INTERVET INC.

PATENT DEPARTMENT

PO BOX 318

MILLSBORO, DE 19966-0318

EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/698,230

Applicant(s)

WAN ET AL.

Examiner

David Lukton

Art Unit

1654

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-41 is/are pending in the application.
- 4a) Of the above claim(s) 24-32 and 39-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Applicants' election of Group II (claims 33-41) with traverse is acknowledged. Also acknowledged are those species that are defined by example 1 (pages 10-13) of the specification. Based on the information provided by example 1, the species elections are as follows:

- a) the specific peptide is SY161;
- b) in the elected method, a filter press is utilized;
- c) sodium sulfite/sodium tetrathionate as the agent that is used to block cysteine residues;
- d) in the elected method, the blocked cysteine residues are not deblocked;

Claims 24-32 and 39-41 are withdrawn from consideration.

Applicants have traversed the restriction by arguing, in effect, that they are not able to see how it is possible that the Group I claims could be obvious over a given reference at the same time that Group II is not obvious over the reference. In response, it is suggested that applicants review the prosecution history of parent application 09/792789. There are several examples of references which render Group I obvious without, at the same time disclosing sulfitolysis. Applicants have also argued that claims 24-32 & 42-43 are generic to Group II. However, this is not true. None of claims 24-32, 42, 43 mention blocking of sulfhydryl groups. Applicants have also argued that they may request

rejoining of claims 24-32 & 42-43 at a later point in the prosecution. Had applicants elected claims 24-32 & 42-43, then rejoining of claims 33-41 might have been justified. But given the election of Group II, rejoining of Group I will not be required. The restriction is maintained.



Claim 33 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of USP 6,995,246. Although the conflicting claims are not identical, they are not patentably distinct from each other; there is overlap of the claimed subject matter.



Claim 33 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of copending application Serial No. 10/873801. Although the conflicting claims are not identical, they are not patentably distinct from each other. [This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented].

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d)



Claims 33-38 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are dependent on a non-elected claim. In addition, the objective of merely “removing particles” is not consistent with the required process step, i.e., sulfitolysis of sulfhydryl groups. Some other, more suitable objective of the claimed method should be stated.



The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 33, 34, 38 are rejected under 35 U.S.C. §103 as being unpatentable over Hsu (USP 6,008,328) in view of Hennen (USP 6,468,534) or Colpan (USP 6,274,371).

Hsu discloses a method for obtaining KGF from lysed bacteria which expressed the KGF. Cell lysis is also disclosed (e.g., col 11, line 10+). Hsu also discloses (col 12, line 25+) removal of endotoxins. Also disclosed (col 11, line 19) is the use of a "filter aid" to clarify the cell lysate. Also disclosed (e.g., col 2, line 56+) is blocking of cysteine sulfhydryl groups.

Hennan discloses (col 10, line 41) that diatomaceous earth is useful for preventing clogging of filters when filtering protein solutions that contain precipitates. Hennan does not disclose a method which comprises removing suspended particles from a lysate, and which method also comprises reducing the amount of DNA and endotoxins.

Colpan discloses a method for removal of cellular debris comprising a filtration step. A preferred filtration aid (col 2, line 31+) is diatomaceous earth. Colpan does not disclose a method which comprises removing suspended particles from a lysate, and which method also comprises reducing the amount of DNA and endotoxins.

Thus, a practitioner of the Hsu invention would purify KGF from lysed bacteria by using various methods including a filtration aid. Hsu discloses the claimed invention, except that there is no specific teaching that the "filter aid" should be diatomaceous earth.

However, a protein chemist in possession of Colpan or Hennan would have recognized

that if a filter aid is used, diatomaceous earth would have been effective for this purpose.

Thus, the claims are rendered obvious.



Claims 33-38 are rejected under 35 U.S.C. §103 as being unpatentable over Hsu (USP 6,008,328) in view of Bobbitt (USP 4923967) further in view of Hennen (USP 6,468,534) or Colpan (USP 6,274,371).

The teachings of Hsu, Hennen and Colpan are indicated above. None of these discloses use of sodium thiosulfate or sodium tetrathionate. Bobbitt discloses (col 3, line 27) a process which comprises sulfitolysis; the sulfitolysis may be achieved (col 5, line 24) by use of sodium thiosulfate or sodium tetrathionate.

Thus, the claims are rendered obvious.



DAVID LUKTON, PH.D.  
PRIMARY EXAMINER

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.